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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,281	10/24/2005	Gunter Fuhr	46955.23	8505

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EXAMINER	
MACAULEY, SHERIDAN R	
ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
11/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,281	FUHR ET AL.	
	Examiner	Art Unit	
	SHERIDAN R. MACAULEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *1-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A response has been received and entered on August 11, 2009. All evidence and arguments have been fully considered. Claims 1-19 are pending. Claims 1-14 have been withdrawn due to a previous requirement for restriction. Claims 15-19 are examined on the merits in this office action.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 15-19 stand rejected under 35 U.S.C. 103(a) as obvious over Fuhr et al. (WO02/46719, see US 2004/0065093 for English translation; both references are cited in a previous action) in view of Kienholz (5,415,282; document cited in IDS). Claim 15 recites a method for storage of at least one suspension specimen in a low-temperature state in a carrier comprising the steps of: accommodating the at least one suspension specimen in at least one specimen chamber made of a flexible material that is elastically deformable at room temperature; positioning the specimen chamber on a first frame part of a mounting frame of the carrier after accommodating the at least on e suspension specimen in the specimen chamber, the mounting frame comprising said first frame part and a second separate frame part, said frame parts adapted for assembling together detachably using one or more connecting elements; connecting the first and second frame parts into an assembled state wherein the first and second frame parts come into contact on side faces of the frame parts and with the specimen chamber, wherein the specimen chamber is securely clamped by the first and second frame parts such that it is immovable relative to the mounting frame; and converting the suspension specimen to a low-temperature state by positioning the carrier with the specimen chamber in cryomedium. Claim 16 recites the method of claim 15, wherein each specimen chamber comprises at least one inlet end and one outlet end, and at

least one suspension specimen is inserted into a corresponding specimen chamber by immersing the inlet end of the corresponding specimen chamber into a specimen reservoir and transferring the suspension specimen under the influence of a vacuum applied to the corresponding outlet end of the specimen chamber, or under the influence of capillary forces. Claim 17 recites the method of claim 15, wherein at least one partial specimen is detached from the at least on specimen chamber in the low temperature state by mechanical separation. Claim 18 recites the method of claim 17, wherein the mechanical separation comprises cutting off chamber sections of the specimen chamber adjacent to the frame parts of the carrier. Claim 19 recites the method of claim 15 wherein each of the first and second frame parts has a circumferential shape.

6. Fuhr teaches a method for storage of a suspension specimen in a low-temperature state in a carrier comprising accommodating the specimen in a specimen chamber that may be made of a flexible material (note that Fuhr discusses the use of a meandering hose that may be closed by clamping together; see English translation, p. 7, par. 82-83), positioning the specimen chamber in a first frame part of a mounting frame of a carrier, which comprises a first and second frame part, which are adapted for assembling together, connecting the first and second frame parts into an assembled state wherein the first and second parts come into contact on side faces with the specimen chamber, and converting the specimen to a low-temperature state by positioning the carrier with the specimen chamber in a cryomedium (see English translation, figs. 17, 18, 21-24, p. 3, par. 24, p. 4, par. 48-49, p. 8, par. 88, 91). Fuhr

teaches the positioning of the flexible material in the mounting frame (see for example, fig. 17) and the closure of the tubes by clamping at a location adjacent to the mounting frame (see again fig. 17 at 614 and p. 7 par. 82). The specimen chambers of Fuhr may comprise an inlet end and an outlet end and may be filled with a suspension specimen by placing the inlet end into a specimen chamber and applying reduced pressure to the outlet end (i.e. the chamber is filled by application of a vacuum or by capillary forces; fig. 21, see English translation, p. 8 par. 88). Fuhr teaches that the frame parts may have a circumferential shape (see figs. 17 and 18 at 621). In the method of Fuhr, at least one partial specimen may be detached from the specimen chamber in the low-temperature state by mechanical separation, such as cutting off chamber sections of the specimen chamber adjacent to frame parts of the carrier (see English translation, figs. 21, 22, p. 5, par. 60, p. 7, par. 80, p. 8, par. 90). Fuhr does not specifically teach the clamping of the specimen chamber in a first and second separate frame part of the mounting frame after accommodating the suspension specimen in the specimen chamber, wherein the specimen chamber is securely clamped by the first and second frame parts.

7. Keinholz teaches a storage container for biological specimens wherein the flexible specimen chamber is securely clamped by two frame parts that are detachably assembled after accommodating the specimen in the container (abstract, figs. 1 and 2).

8. At the time of the invention, a method for storage of biological specimens comprising nearly all of the claimed elements was known, as taught by Fuhr. It was further known in the art that flexible containers comprising biological specimens could be clamped between two frame parts that may be assembled detachably, as taught by

Keinholz. One of ordinary skill in the art would have been motivated to modify the teachings of Fuhr such that the clamping mechanism for the specimen chambers was integrated into the frame elements because Fuhr teaches the positioning of the flexible material into the mounting frame (see fig. 17), the filling of the meandering hose that serves as the specimen chamber (see p. 7, par. 80) and the closure of the tubes by clamping adjacent to the mounting frame (see fig. 17 at 614 and p. 7 par. 82). Since Keinholz teaches that the clamping mechanism could be integrated into frames in methods for the encapsulation of biological specimens, one of ordinary skill in the art would have recognized that, after the filling of the tubes, a frame element could have been placed over the assembly to clamp the tubes rather than individually clamping each of the specimen chambers. One would further have recognized that this would have been desirable because it eliminates the additional step of clamping individual specimen chambers. Furthermore, after clamping a circular hose, as depicted in the invention of Fuhr (see fig. 17), the circumference of the hose would be encompassed in the clamp, and thus the shape of the frame parts serving as the clamp would be circumferential. Since such clamping mechanisms were known to be suitable for the storage of biological specimens at the time of the invention, one of ordinary skill in the art could have performed such a method with a reasonable expectation of success. It would therefore have been obvious for one of ordinary skill in the art to modify the teachings discussed above to arrive at the claimed invention.

9. Thus, the claims are anticipated by or, in the alternative, are rendered obvious by the cited reference.

Response to Arguments

10. Applicant's arguments filed August 8, 2009 have been fully considered but they are not persuasive. Applicant argues that the prior art does not render the claimed invention obvious because one of ordinary skill in the art would not have been motivated to combine the cited references to arrive at the claimed invention. Specifically, applicant argues that one would not have been motivated to modify the teachings of Fuhr such that the frame parts come into contact with the specimen chamber such that the specimen chamber is securely clamped by the first and second frame parts. It is noted, however, that Kienholz provides motivation for one of ordinary skill in the art to modify the teachings of Fuhr to include this feature. As discussed above, Keinholz teaches a storage container for biological specimens wherein the flexible specimen chamber is securely clamped by two frame parts that are detachably assembled after accommodating the specimen in the container. Since Keinholz teaches that the clamping mechanism could be integrated into frames in methods for the encapsulation of biological specimens, one of ordinary skill in the art would have recognized that, after the filling of the tubes, a frame element could have been placed over the assembly to clamp the tubes rather than individually clamping each of the specimen chambers. One would further have recognized that this would have been desirable because it eliminates the additional step of clamping individual specimen chambers. Although Keinholz teaches that the flexible specimen chamber is a plastic bag rather than a tube such as the flexible plastic tubing of Fuhr, one of ordinary skill in the art would recognize that a

method using a flexible container for the storage of liquids would be suitable for use with a bag or flexible tubing, as both types of storage containers were known in the art to be useful for the same purposes in similar storage systems, as taught by the cited prior art. Therefore, applicant's arguments have been fully considered, but they have not been found to be persuasive.

Conclusion

No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/

Primary Examiner, Art Unit 1651